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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *et al.* *ex rel.* JOHN MILLER,

Plaintiffs,

v.

CARECORE NATIONAL LLC *et al.*,

Defendants.

UNITED STATES OF AMERICA,

Plaintiff,

v.

CARECORE NATIONAL, LLC,

Defendant.

Case No. 13-CV-1177 (RJS)

COMPLAINT-IN-INTERVENTION OF THE UNITED STATES OF AMERICA

Jury Trial Demanded

Plaintiff the United States of America, by its attorney, Joon H. Kim, Acting United States Attorney for the Southern District of New York, alleges upon information and belief as follows:

INTRODUCTION

1. This is a civil fraud action brought by the United States of America (the "Government") against the defendant CareCore National, LLC ("Defendant," "CareCore," or the

"Company") under the False Claims Act, 31 U.S.C. §§ 3729-33 (the "FCA"), to recover treble damages and penalties resulting from Defendant knowingly presenting or causing to be presented to the Government false claims for payment, or knowingly making or using, or causing to be made or used, false records or statements material to false claims for payment under the Medicare Program, Title XVIII of the Social Security Act of 1965, 42 U.S.C. § 1395 *et seq.*, and the Medicaid Program, Title XIX of the Social Security Act of 1965, 42 U.S.C. § 1396 *et seq.*, in connection with Defendant's "Process As Directed" or "PAD" Program.

2. As described in more detail below, CareCore contracted with insurers, including managed care organizations participating in the Medicare Part C and Medicaid Managed Care programs ("MCOs"), to process prior authorization requests for medical procedures made by treating physicians. Specifically, Defendant was required to determine based on objective medical evidence whether the requested procedure was medically necessary and reasonable (a "prior authorization").

3. Pursuant to Defendant's contracts with insurers, Defendant was required to process the prior authorization requests within four to 48 hours after receiving them, depending on the urgency of the request, or be subject to contractual performance penalties. Defendant, however, was unable to process requests in a timely fashion. Instead, starting in at least as early as 2005, the Company instructed employees, who were not physicians, to "auto-approve" large batches of prior authorization requests without any review, *i.e.*, to falsely certify the prior authorization requests as medically necessary and reasonable without physician review. The Company thereafter formalized this process, commonly referred to by employees of the Company as "padding," including by developing a formal corporate policy with extensive training materials and internal reporting requirements. This formalization was based upon

management's determination that falsely certifying the prior authorization requests was more cost effective than hiring more physicians to review the prior authorization requests. The PAD Program also ensured that Defendant would not suffer contractual penalties for failing to timely process prior authorization requests.

4. As a result of the fraud committed by CareCore in connection with the PAD Program, the Company "padded" (*i.e.*, approved without physician review) hundreds of thousands of prior authorization requests, resulting in tens of millions of dollars of false claims being submitted to insurers administering Federally Funded Healthcare programs, which were then paid using federal funds.

JURISDICTION

5. This Court has jurisdiction over the claims brought under the False Claims Act pursuant to 31 U.S.C. § 3730(a) and 28 U.S.C §§ 1331 and 1345, and pursuant to the Court's general equitable jurisdiction.

6. Venue lies in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1391(c), because Defendant does business in this District and many of the acts complained of herein took place in this District.

PARTIES

7. The United States of America, as plaintiff, brings this action on behalf of its agency the United States Department of Health and Human Services ("HHS").

8. Defendant CareCore National LLC is a limited liability company organized under the laws of the State of New York, with its principal place of business located at 400 Buckwalter Place Boulevard, Bluffton, South Carolina. In 2015, CareCore became part of eviCore healthcare.

9. Relator John Miller is a former employee of CareCore who worked as a Clinical Reviewer and supervisor, and currently resides in the State of Colorado.

LEGAL FRAMEWORK

10. The United States, through HHS, administers both the Medicare Program for the aged and disabled, established by Title XVIII of the Social Security Act, *see* 42 U.S.C. §§ 1395 *et seq.*, and Medicaid, established in Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq.* Medicaid is administered by the states, but is funded jointly by the federal and state governments.

11. Through Medicare Part C, 42 C.F.R. Part 422, and Medicaid Managed Care, 42 C.F.R. Part 438, Centers for Medicare and Medicaid Services ("CMS") authorizes private insurers to offer health insurance plans to individuals who are eligible for Medicare and Medicaid. The private insurance plans offered through Medicare Part C and Medicaid Managed Care are paid for in full by federal and/or state government funds.

12. The private insurers offering plans through Medicare Part C and Medicaid Managed Care, known as managed care organizations ("MCOs"), contract with CMS and/or with state agencies to administer Medicare Part C and Medicaid Managed Care benefits, and are required to provide the same level of service as available through traditional Medicare or Medicaid. All of the protections and regulations applicable to Medicare and Medicaid apply to the practices of the MCOs. Pursuant to those contracts, the MCOs are paid a capitated rate based on the number of Medicare and Medicaid beneficiaries they service and the level of sickness of those beneficiaries.

13. Medical procedures undergone by the beneficiaries who participate in the MCOs' Medicare Part C or Medicaid Managed Care plans are billed to the MCOs for payment. Any and

all such insurance claims paid by MCOs, as well as the MCOs' associated administrative costs, are paid using funds provided by CMS and the states through the capitated payments.

14. The MCOs' contractual obligations and the applicable regulations require that the MCOs have the proper system in place to ensure that they only pay for services that are determined to be medically necessary and reasonable based on objective medical criteria; that requirement also applies to entities that contract with the MCOs. *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A); 42 U.S.C. § 1396a(a)(30)(A); 42 C.F.R. § 411.15(k)(1), (13), (15); *see also Beal v. Doe*, 432 U.S. 438, 444 (1977).

FACTS

I. Background on CareCore's Operations

15. CareCore contracts with MCOs to manage their prior authorization process on an outsource basis. Those contracts require that CareCore make its prior authorization decisions based on objective medical criteria, as mandated by the applicable regulations.

16. The prior authorization process is a material component of the MCOs' insurance claims process. Specifically, only after a procedure is preauthorized (and occurs), can the provider submit a claim for payment to the MCOs. Accordingly, the MCOs that contract with CareCore rely on its prior authorization determinations in paying insurance claims submitted by providers.

17. CareCore has two types of employees who are directly involved in the prior authorization process: Clinical Reviewers and Medical Directors.

18. CareCore's Clinical Reviewers are licensed healthcare nurses, registered nurses or licensed practical nurses (R.N.s or L.P.N.s), and radiology technicians under the supervision of R.N.s and/or L.P.N.s, who are trained to assess prior authorization requests. Clinical Reviewers are authorized to approve prior authorization requests if they meet certain pre-set objective

medical criteria, but cannot deny a prior authorization request; instead, if the claim does not meet the pre-set objective medical criteria, the clinical reviewers must refer the request to a Medical Director for further review and determination.

19. CareCore's Medical Directors are physicians who hold current unrestricted licenses as doctors of medicine (M.D.) or osteopathic medicine (D.O.). Medical Director physicians are board-certified in the area of specialty in which they render their professional opinions. Medical Director physicians have authority to approve or deny prior authorization requests.

20. CareCore has a proprietary software system, which Clinical Reviewers use to obtain and record information related to prior authorization requests. That software system has two relevant components: (1) the centralized database that contains the information about the request and how it is processed, and (2) the analytical software that generates a recommendation based on the medical information entered into the system.

21. CareCore receives prior authorization requests from treating physicians via telephone, fax, or through CareCore's Internet portal.

22. When a prior authorization request comes in by telephone or fax, it is routed to intake department personnel, who are non-clinical clerks that create an entry in the database related to the request. Requests for prior authorization via the Internet are not handled by intake personnel, but rather are automatically sent for review by a Clinical Reviewer.

23. After the intake process is complete, the request is directed to a Clinical Reviewer, who takes over the request. Using the information provided by the requestor, which may be supplemented through dialogue with the requestor, the Clinical Reviewer inputs relevant medical information into CareCore's proprietary software.

24. Based on the information provided by the requestor and inputted by the Clinical Reviewer, the proprietary software generates a recommendation either to approve the request or send the request for further review by a physician. If the software recommends approval, the Clinical Reviewer approves the request, and that approval is sent to the MCO. If the software recommends further review, then the Clinical Reviewer transfers the request to an electronic queue of requests awaiting further review by a Medical Director (the "Medical Review Queue").

25. Once a Clinical Reviewer places a prior authorization request into the Medical Review Queue, the next step is for a Medical Director to review the available information and determine whether or not to deny the prior authorization request.

26. Generally, at the end of each day, CareCore's prior authorization determinations are transmitted to CareCore's client insurers to be used in their claims processes.

27. Since 2005, CareCore has processed millions of prior authorization requests.

28. Prior authorization requests can have different priority designations. Most cases are designated "regular" priority; for those requests, CareCore is generally required pursuant to its contracts with its client insurers to approve or deny the prior authorization request within two days. For cases that are deemed "urgent," a prior authorization request must be approved or denied within four hours.

29. If CareCore fails to process a prior authorization request within these time constraints on a repeat basis, then pursuant to its contracts with its client insurers, CareCore is subject to substantial penalties.

II. The PAD Program

30. Starting in at least 2005, CareCore became unable to timely process the volume of prior authorization requests that it was receiving, CareCore developed and implemented a

corporate policy and program known as the Process As Directed, or PAD Program, to automatically approve pre-authorizations without the required assessment of medical necessity and reasonableness. When Clinical Reviewers auto-approved prior authorization requests in accordance with the PAD Program, they often referred to this improper practice as "padding." The prior authorization requests improperly approved through the PAD Program ("padded requests") were transmitted to CareCore's client insurers, including MCOs, as preauthorized requests.

31. Pursuant to the PAD Program, CareCore's Clinical Reviewers would approve prior authorization requests that were in the Medical Review Queue awaiting independent evaluation by Medical Director, *i.e.*, CareCore had already made the determination that the prior authorization request could not be approved based on the information provided. Approvals made through the PAD Program were not based upon an evaluation of objective medical criteria or a Medical Director's independent review of the request. Rather, Clinical Reviewers simply approved vast numbers of prior authorization requests on the Medical Review Queue without having obtained any new objective medical information about the request.

32. CareCore engaged in padding in order to avoid contractual penalties it would have incurred for failing timely to review the prior authorization requests. One high-level executive at CareCore explained that padding was necessary because CareCore had run "out of time to make a decision and thus would be out of compliance with the State/Fed and health plans (big fines, license issues etc.)."

33. The PAD Program was formalized into corporate policy, including daily reporting of the number of "padded" prior authorization requests to high-level executives at CareCore.

34. CareCore developed training materials designed to prepare its employees to efficiently auto-approve prior authorization requests.

35. In a training presentation, Defendant set forth a highly structured procedure for "padding," which involved multiple levels of priority. The presentation related to specific insurance plans, was broken down by the type of medical procedure requested, and divided the labor between multiple teams working in shifts.

36. The training materials also explain how the CareCore employees engaged in "padding" should record their activities in the database, and how they should purposefully obfuscate what they were doing: "Do not document anything in the journal about padding!"

37. From 2005 through 2013, CareCore padded more than two hundred thousand prior authorization requests.

38. In CareCore's role managing the prior authorization process, it was required by contract and federal and state regulations to ensure that the requested medical procedures were preauthorized based solely on objective medical criteria. Each time CareCore transmitted a "padded" prior authorization request to an MCO, thereby approving the request without regard to whether it was medically necessary or reasonable, CareCore knowingly or recklessly made a false statement to the MCO that Carecore had reviewed and approved the pre-authorization request in compliance with contractual and regulatory requirements.

39. Had MCOs known that CareCore's "padded" prior authorizations of medical procedures were not actually based upon any true assessment of medical necessity and reasonableness, the MCOs would not have paid claims for those procedures. As a result of CareCore's deception, MCOs ended up paying claims for hundreds of thousands of medical procedures based upon the mistaken belief that the procedures being billed for had actually

received a valid prior authorization. Therefore, the PAD Program resulted in false insurance claims related to the padded requests being presented to the MCOs for payment with federal and/or state government funds.

40. In paying insurance claims with federal funds, MCOs relied upon the false statements contained in the padded prior authorizations, namely that CareCore had determined that the requested procedure was medically necessary and reasonable based on objective medical criteria.

41. As a result of CareCore's PAD Program, MCOs spent tens of millions of dollars in federal and/or state government funds paying for and/or reimbursing medical procedures that were improperly preauthorized by CareCore.

42. By virtue of the false statements that Defendant made, which were incorporated into claims to the MCOs and/or the false claims that Defendant knowingly caused to be presented to the MCOs, the United States suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

COUNT I
Violations of the False Claims Act: Presenting False Claims for Payment
(31 U.S.C. § 3729(a)(1) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(A))

43. All of the foregoing allegations are incorporated by reference as though fully set forth herein.

44. As a result of the foregoing conduct, CareCore knowingly presented or caused to be presented false or fraudulent claims for payment to a recipient of federal funds to be spent or used on the Government's behalf and to advance federal healthcare programs, in violation of 31 U.S.C. § 3729(a)(1)(A).

45. After receiving CareCore's prior authorizations, the healthcare providers, who performed the procedures approved via the padded requests, submitted claims for those falsely preauthorized services to the MCOs, who paid those claims with government funds pursuant to federal healthcare programs.

46. As a result of CareCore's actions as set forth above in this Complaint-in-Intervention, plaintiff United States of America has been damaged.

COUNT II
Violations of the False Claims Act: Use of False Statements
(31 U.S.C. § 3729(a)(2) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(B))

47. All of the foregoing allegations are incorporated by reference as though fully set forth herein.

48. As a result of the foregoing conduct, CareCore knowingly made, used, or caused to be made or used, false or fraudulent records or statements material to the payment of false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(1)(B).

49. When CareCore padded a prior authorization request, it falsely stated that it had determined the padded request as medically necessary and/or reasonable based on objective medical criteria, while knowing that it had failed to perform this analysis despite being legally and contractually obligated to do so.

50. CareCore's false statements were material to the payment of the associated claim because, *inter alia*, a claim made to an MCO administering Medicare and Medicaid programs will not be paid without prior authorization of the procedure.

51. Healthcare providers who performed the procedures associated with the padded requests incorporated CareCore's padded authorizations into claims for payment made to MCOs,

who administer Medicare and Medicaid programs, and those claims were paid using funds provided by CMS.

52. As a result of CareCore's actions as set forth above in this Complaint-in-Intervention, the United States of America has been damaged.

WHEREFORE, the United States requests judgment against Defendant as follows:

(a) Imposing trebled damages against Defendant;

(b) Imposing civil penalties against Defendant up to the maximum allowed by law;

(c) For costs of suit; and

(d) For such further relief that the Court deems just and proper.

Dated: New York, New York
April 21, 2017

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